IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COREY RUSS AND CHRIS MURPHY, Plaintiffs,	**CIVIL ACTION**
v.	
NORTH AMERICAN RESCUE, LLC, et al.	**NO. 21-4238**
Defendants.	

OPINION

Plaintiff-Relators Corey Russ and Chris Murphy ("Plaintiffs") bring this *qui tam* action alleging three counts of violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(B). Each defendant—North American Rescue, LLC ("NAR"), C-A-T Resources, LLC ("CATR"), and Henry Schein, Inc. ("Schein"), which Plaintiffs allege is the parent company of NAR—individually moved to dismiss Relators' claims pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, Schein's Motion will be granted; NAR's and CATR's Motions will be denied.

I. BACKGROUND

This case is about the allegedly fraudulent sale of military medical equipment. Plaintiffs are two former Army combat medics. They were not employed by Defendants, as *qui tam* relators often are—they worked for other companies that, like Defendants, make emergency medical equipment. Defendants are engaged together in the sale of certain medical equipment to the United States military, through the Department of Defense ("DoD"). According to Plaintiffs, CATR "held itself out to the public as the manufacturer of" the Combat Application Tourniquet (CAT), a fabric-and-plastic device designed to be used "by first responders in battlefield or other

emergency conditions" to staunch bloodflow from a severely injured limb. CATR sells to DoD through NAR, its exclusive U.S. distributor. NAR sells other products to DoD as well. And Schein, Plaintiffs say, has "owned, operated and managed" NAR "[s]ince at least March 2019."

Plaintiffs allege that Defendants defrauded the U.S. Government in two ways: First, by inaccurately representing the country of origin of some of the products they sold to DoD; second, by inaccurately representing the sterilization status of some of the products they sold to DoD. Specifically, Plaintiffs allege in Count One that NAR, CATR, and Schein "have knowingly sold hundreds of millions of dollars' worth of Chinese-made medical supplies to the Government while fraudulently misrepresenting the products' compliance" with certain statutes that require certain products sold to the Government to be made exclusively in the United States; they allege in Counts Two and Three that NAR and Schein "have knowingly falsely represented that certain medical supplies [sold to the Government] were properly sterilized," as required by the U.S. Food and Drug Administration ("FDA"). Plaintiffs claim Defendants have "enrich[ed] themselves at the expense of American taxpayers" to the tune of $400 million.

The FCA "imposes civil liability on anyone who 'knowingly presents . . . a false or fraudulent claim for payment or approval' to the United States Government." *United States ex rel. Charte v. Am. Tutor, Inc.*, 934 F.3d 346, 351 (3d Cir. 2019) (quoting 31 U.S.C. § 3729(a)(1)(A)). Under the FCA, private parties ("relators") may bring a *qui tam* civil action for the person and for the United States Government against the alleged false claimant, in the name of the Government." *Id.* (quotations removed). The Government may choose to intervene, but if it does not (as it did not here), the relators have "the right to conduct the action." *Id.*

Two statutes underpin Plaintiffs' claims: the Berry Amendment and the Trade Agreements Act ("TAA"). Plaintiffs are not suing *pursuant to* these statutes; rather, they claim

that Defendants violated the FCA because, Plaintiffs say, Defendants certified they were complying with the Berry Amendment and the TAA when in fact they were not. The Berry Amendment prohibits DoD from spending appropriated funds on textiles and other materials that are not "grown, reprocessed, reused, or produced in the United States."[1] The Trade Agreements Act ("TAA") allows the Government to purchase materials from designated countries notwithstanding the domestic-purchase mandate in the Buy American Act.[2] China is not one of the TAA's designated countries.[3]

The heart of Plaintiffs' origin-misrepresentation claim is that since 2015 NAR has sold DoD millions of dollars' worth of CATs, "medical kits" (collections of devices intended to be carried together, typically including a CAT and other products), and other products each year, and that many of those products were in fact produced in China. They allege further that Schein bought NAR in 2019, that Schein "exercise[es] ultimate control over NAR's operations," and that Schein has benefitted financially from NAR's sales.

In sum, Plaintiffs claim that Defendants have violated the FCA by falsely representing to the Government that these devices[4] were made in the United States—that is, that they were Berry-Act- and TAA-compliant; and that that Defendants NAR and Schein violated the FCA by

---

[1] 10 U.S.C. § 4862(a)-(b).

[2] The Buy American Act is codified at 41 U.S.C. § 8301 *et seq.* The TAA is codified at 41 U.S.C. § 8302.

[3] Defendants do not challenge Plaintiffs' characterization of the Berry Amendment, the Buy American Act, or the TAA.

[4] "[T]he CAT; Compressed Gauze; ETDs; ARS Needles; tracheostomy kits; Spider Straps; Talon Litters; emergency hypothermia blankets; backboards; BVMs; and EENT kits, including these products as sold individually, as a family or series of products, and as part of a medical kit."

falsely representing to the Government that certain devices were sterilized when in fact they were not.

II. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* The complaint is construed "in the light most favorable to the plaintiff" to determine "whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). The Court "tak[es] note of the elements [that] must [be] pled to state a claim[,]" *Oakwood Lab'ys LLC v. Thanom*, 999 F.3d 892, 904 (3d Cir. 2021) (quotation omitted) (alteration in original) then—taking all non-conclusory well-pleaded facts as true—determines whether those facts state a "plausible claim for relief." *Fowler*, 578 F.3d at 210-11.

Federal Rule of Civil Procedure 9(b) requires additional specificity in cases involving fraud claims, as is the case here. "In alleging fraud," plaintiffs "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. (9)(b). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id.* But "plaintiffs must still allege facts that show the court their basis for inferring that the defendants acted with 'scienter.'" *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997).

And, specifically as to FCA claims, "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153, 157-58 (3d Cir 2014) (quotations removed).

III. DISCUSSION

A. FCA Claims

i. Essential Elements of FCA Claims

The FCA imposes liability on someone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the Government or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). A FCA violation, therefore, "includes four elements: falsity, causation, knowledge, and materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017).[5]

A false or fraudulent claim "may be either factually false or legally false." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018) (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011), *overruled on other grounds as recognized by United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101 (3d Cir. 2018)). A claim is factually false when "the claimant

[5] The Third Circuit "sometimes recounts these elements differently." *United States ex rel. Allstate Ins. Co. v. Phoenix Toxicology & Lab Servs., LLC*, 2024 WL 2785396, at *7 (D.N.J. May 30, 2024). *See, e.g.*, *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019) ("[R]elators must plead three elements: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and, (3) the defendant knew the claim was false or fraudulent.") (quotations omitted). Here, as will be explained below, NAR's and CATR's Motions to Dismiss attack only Plaintiffs' allegations as to falsity, so both stylizations of the elements would lead to the same conclusions.

misrepresents what goods or services . . . it provided to the Government," and it is legally false when "the claimant lies about its compliance with a statutory, regulatory, or contractual requirement." *Id.*

ii. Rule 9(b) in the FCA Context

Rule 9's heightened pleading standard applies to FCA claims. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004). And "the degree of detail required to satisfy [Rule 9(b)] often turns on the substantive context in which the fraud is alleged to have occurred." Wright and Miller, 5A Fed. Prac. & Proc. Civ. § 1298 (4th ed.).

A FCA Rule 9 analysis is a balancing act. On the one hand, Rule 9's heightened pleading standard protects defendants from easily lobbied but flimsily supported allegations of bad-faith conduct. On the other hand, holding plaintiffs to too high a pleading standard before discovery risks rewarding defendants who have concealed their fraud so successfully that plaintiffs with meritorious claims do not have enough information to get to discovery. *See Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) ("Courts must be sensitive to the fact that application of Rule 9(b) prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud.") (quotations removed).[6]

Specifically, "Rule 9(b)'s particularity requirement requires a [FCA] plaintiff to allege all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue." *United States ex rel.*

---

[6] The Fifth Circuit has analyzed Rule 9(b) persuasively: "Rule 9(b)'s objectives of ensuring the complaint provides defendants with fair notice of the plaintiffs' claims, protects defendants from harm to their reputation and goodwill, reduces the number of strike suits, and prevents plaintiffs from filing baseless claims then attempting to discover unknown wrongs." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (quotations removed).

Bookwalter v. UPMC, 946 F.3d 162, 176 (3d Cir. 2019) (quotations removed). Critically, though, a FCA plaintiff need not "plead anything more, such as the date, time, place, or content of every single allegedly false [] claim." *Id.*

B. Initial Matters

i. Schein's Motion to Dismiss

Plaintiffs do not bring any allegations against Schein alone. Their claims against Schein derive from their claims against NAR and CATR: "From March 2019 to the present," Plaintiffs allege, "Henry Schein knowingly participated in the false and fraudulent conduct alleged herein." They allege that "the profits from NAR's business and the fraudulent schemes alleged herein flowed to [] Schein," that "NAR operated with the knowledge and approval of [] Schein," and that "Schein t[ook] advantage of NAR's contracts with the Government to insert and sell [] Schein-branded products into the medical kits delivered to the Government." They allege that Schein "allowed NAR" to engage, and "did not stop NAR from" engaging in, fraudulent conduct.

The thrust of Schein's Motion is that Plaintiffs do not actually allege any fraudulent conduct by Schein specifically. It makes three arguments: First, that Plaintiffs simply "lump" the Defendants together throughout the complaint, and, in any case, that they have not "alleged facts sufficient to show that Schein did anything to violate the FCA," so their allegations "ha[ve] nothing to do with what Schein supposedly did or failed to do and whether such act or omission gives rise to a false claim under the FCA"; second, that piercing the corporate veil to assign liability to Schein is inappropriate because Plaintiffs "do[] not articulate a viable basis by which Schein and NAR should be treated as a single entity for FCA liability"; and, third, that Plaintiffs improperly plead "upon information and belief."

Schein's first argument—that Plaintiffs have not actually alleged any fraudulent conduct by Schein itself—disposes of the matter. FCA liability arises when "it [can] be fairly said" that a defendant "knowingly assisted in causing the government to pay claims which were grounded in fraud." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) (citing *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 544 (1943), *superseded by statute on other grounds as recognized by Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 412, (2011)). And "[a] parent corporation can be held liable for the conduct of its subsidiary if it was *directly involved* in submitting false claims or causing them to be submitted to the government." *United States v. Kindred Healthcare, Inc.*, 469 F. Supp.3d 431, 454 (E.D. Pa. 2020) (emphasis added). Here, even if Plaintiff has averred enough to suggest that Schein owns and benefits financially from NAR, ownership alone, without "direct[] involve[ment]", does not give rise to liability.[7]

Plaintiffs contend they "do not seek to hold Schein liable merely because it is NAR's parent company," but rather because Schein was "direct[ly] involve[d] in the fraudulent scheme" via

> (1) direct control of NAR's business operations; (2) managing and supervising NAR's conduct in selling to the Government; (3) failing to properly prevent NAR from submitting false claims; (4) failing to require NAR to mark its products with the proper country of origin; (5) encouraging NAR to continue selling nonconforming goods to the Government; and, (6) directly benefitting from NAR's misconduct by adding Schein-branded products to the medical kits sold to the Government.

---

[7] In fact, even if Plaintiffs have averred enough to suggest Schein's awareness of any fraud, awareness alone has been found not to be enough by other district courts in this circuit which have held that "inaction despite knowledge of an alleged fraudulent scheme is distinguishable from direct participation in a scheme." *United States ex rel. Polansky v. Exec Health Res., Inc.*, 196 F. Supp.3d 477, (E.D. Pa. 2016) (citing *US ex el. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D 113, 125-26 (W.D. Pa. 2006) (noting that allegations that a corporate defendant and its parent company "stood and watched . . ." were insufficient because "no liability attaches under the FCA for their inaction").

But none of these—even if taken as true—constitutes direct involvement. Plaintiffs have not alleged that Schein itself directly participated in the scheme.

Schein argues that "[t]here are no allegations that Schein was directly involved in the manufacture, promotion, sale, or distribution of the medical equipment at issue, or that Schein had any role in the submission of any false claims to the government for payment for such equipment," and it is correct. In short, as Schein says in its Reply, Plaintiffs' operative complaint does not "contain allegations identifying any specific, direct acts that Schein undertook that could constitute fraud." Accordingly, Schein's Motion will be granted, and Plaintiffs' claims as to Schein will be dismissed without prejudice.

ii. CATR's Argument Regarding Public Disclosure and Original Source

CATR raises the FCA's public-disclosure bar. The public-disclosure bar provides that a court must dismiss an FCA claim if "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in a public forum,[8] unless "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2010); *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018). (In other words, a plaintiff cannot maintain an FCA claim if the alleged fraud was already public, unless the plaintiff was the one

---

[8] The statute lists the applicable fora:

> (1) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> (2) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or,
> (3) from the news media.

31 U.S.C. § 3730(e)(4)(A)(i)-(iii).

who provided the public information.) The public-disclosure bar is an affirmative defense, not a jurisdictional bar. *See United States v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018) ("As amended effective March 23, 2010, the [public-]disclosure bar is no longer jurisdictional.").

"On a Rule 12(b)(6) motion, an affirmative defense . . . is appropriately considered only if it presents an insuperable barrier to recovery by the plaintiff." *Flight Sys., Inc. v. Elec. Data Sys. Corp.*, 112 F.3d 124, 127 (3d Cir. 1997). And, "affirmative defenses that are not listed in Rule 12(b) c[an] still be made by motion, provided that the basis of the defense was apparent on the face of the complaint." *Ball v. Famiglio*, 726 F.3d 448, 459 n.16 (3d Cir. 2013), *abrogated in part on other grounds by Coleman v. Tollefson*, 575 U.S. 532, 135 (2015).

Here, the basis of CATR's affirmative defense seems to be that Plaintiffs' information regarding Defendants' manufacturing capacity came from a public disclosure in the form of a "publicly available video" showing, as Plaintiffs explain, "CATR employees working in a facility that contained only basic packaging equipment," that was referenced in an earlier version of Plaintiffs' complaint. But the operative complaint does not mention the video, and the Court cannot consider any material in earlier versions of the complaint.[9] Because CATR has not identified any public disclosure, the public-disclosure bar does not apply, and Plaintiffs need not

[9] The parties—especially Defendants, and particularly CATR—repeatedly invite the Court to consider material in the previous version of Plaintiffs' complaint, including material regarding the video. But when deciding a Motion to Dismiss the Court cannot consider anything in a previous version of the complaint or draw any substantive inferences from any differences between versions. *See Palakovic v. Wetzel*, 854 F.3d 209, 220 (3d Cir. 2017) ("[A]n amended pleading . . . supersedes the earlier pleading and renders the original pleading a nullity."); *W. Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 173 (3d Cir. 2013) ("[A]t the motion[-]to[-]dismiss stage, when the district court typically may not look outside the four corners of the amended complaint, the plaintiff cannot be bound by allegations in the superseded complaint.")

substantiate their credentials as an "original source."[10]

C. NAR's and CATR's Motions to Dismiss

i. Count One: False Certification of Compliance with Berry Amendment and TAA (Against All Defendants)

As noted above, FCA plaintiffs must show "falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. The heart of Plaintiffs' false-certification claim is that Defendants knowingly "falsely represented" that the CAT and other products "complied with the Berry Amendment and TAA, despite the fact that at least some of these products or materials originated in China" (and were therefore Berry-Amendment- and TAA-noncompliant).

In their Motions, NAR and CATR attack Plaintiffs' claims on falsity grounds only. That is, they do not challenge Plaintiffs' allegations of causation, knowledge, or materiality—they argue only that Plaintiffs have not alleged enough to reasonably give rise to the inference that their representations as to the products' country of origin were false. Still, in that Plaintiffs' allegations differ as to NAR and CATR, NAR's and CATR's Motions will be addressed separately, in turn.

a. NAR's Motion to Dismiss

1. Plaintiffs' NAR-Specific Allegations[11]

Because NAR attacks falsity only, the analysis rises or falls on one point: whether

[10] In any case, even if the Court could consider the parties' characterizations of the video footage, the video alone would not likely subject Plaintiffs to the public-disclosure bar. The bar only applies when there has been public disclosure of both the fraud allegations and the essential elements of the fraud, not just public disclosure of one or two of the facts that ultimately support the claim. *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 84 (3d Cir. 2018).

[11] Many of Plaintiffs' allegations refer to multiple defendants. They are separated here where possible to clarify the analysis.

Plaintiffs have alleged enough to plausibly suggest that certain products NAR sold to DoD were in fact made in China. [12]

Rule 9(b) requires that FCA Plaintiffs "provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a *strong inference* that claims were actually submitted." *United States v. Omnicare, Inc.*, 903 F.3d 78, 91 (3d Cir. 2018) (quotations removed and emphasis added).

NAR argues that Plaintiffs have not provided enough factual information to properly give rise to a strong inference, and that instead Plaintiffs' false-certification claim consists of mere "dots," which to "connect" Plaintiffs "rely . . . on their own unsupported assumptions"—instead of alleging sufficient facts. NAR argues that Plaintiffs "do not . . . identify a single CAT that any defendant sold and delivered to the government[that] was manufactured in and imported from China," and that they never explain "whether or how" any of the other products "are tied to any submission of a false or fraudulent claim for payment or approval" (quotations removed). "Such speculation," NAR contends, "is insufficient to plead a viable FCA claim."

Plaintiffs respond that they have "not only set forth particular details of a scheme to submit false claims but ha[ve] additionally supported them with *solid evidence* that would allow for a strong inference that false claims were actually submitted." The evidence set forth by Plaintiffs can be categorized into three 'buckets': First, NAR imported significant quantities of Chinese-made materials and products; second, NAR re-packaged Chinese-made products to

---

[12] NAR confirms in its Reply that while it "contests that [Plaintiffs] can satisfy the other elements for a viable FCA claim[] (*i.e.*, causation, scienter, and materiality)," it is not rebutting those because doing so "would require evidence and other materials that are not appropriate for consideration of a motion to dismiss." NAR misstates the standard—facts are assumed true, not "rebutted," at the motion-to-dismiss stage—but, in any case, it is clear NAR focuses only on falsity.

conceal their true origins; and, third, NAR does not have the manufacturing capacity in America to produce the products it sells to DoD (and therefore the products must have been produced elsewhere). These three buckets combine, Plaintiffs argue by implication, to "provide the level of detail required" to survive a motion to dismiss, even under Rule 9(b)'s heightened standard.

Indeed, Plaintiffs provide significant detail as to all three 'buckets' of allegations.

First, they allege facts to establish that NAR does indeed import materials from China. Plaintiffs allege that "U.S. Customs and Border Protection ('CBP') recorded multiple shipments from companies located in East Asia to NAR's headquarters," including "more than 25 tons of textile products to NAR from China Surgical Dressings Center Co.," which makes "cloth medical products such as bandages, gauze and facemasks." These shipments, Plaintiffs allege, "consisted of medical bandages, gauze, wadding and similar articles," and "[a]t least one shipment from China Surgical Dressings to NAR originated in Ningbo, China."

They further allege that NAR has received products from a Chinese company called Golden Season PTE, Ltd. ("Golden Season"). Golden Season, say Plaintiffs, is "a warehouse and wholesale trader" in Singapore and "the products it sells to NAR, are produced in China." Plaintiffs allege that NAR knows Golden Season makes its products in China and that Golden Season has even "shipped goods to NAR directly from China rather than routing them through Singapore."[13] Plaintiffs further allege that NAR and Golden Season are intertwined—they say that Golden Season "advertised many of [its] products using the same brand names . . . that NAR

[13] For instance, Plaintiffs allege, "[o]n November 16, 2015, NAR purchased a shipment of litter stands, field hospital beds, litter carriers and 'Raptor Securing Bands' from Golden Season. Golden Season shipped these goods to NAR from the Port of Yantian, which is a deep-water port in Shenzhen, China."

has used to sell the same products in the United States."[14]

Furthermore, Plaintiffs allege, Golden Season explicitly connected its production to NAR: Its website referred to the "'Raptor Securing Bands' NAR purchased from it in 2015" as the "'NAR IV Securing Device,'" and it likewise "advertised a 'NAR Hypothermia Prevention and Management Kit,'" which Plaintiffs allege NAR "advertised . . . to American customers under precisely the same name." They also allege Golden Season has directly shipped products to NAR: "CBP recorded no fewer than twelve separate shipments of emergency blankets from Golden Season to NAR" that "originated in Shanghai, China and Ningbo, China"—blankets that Plaintiffs say Golden Season advertised as the "Golden Season Thermal Blanket" and NAR advertised as the "NAR Survival Blanket." Specifically, as to the CAT, Plaintiffs allege that Golden Season "advertised the CAT on its website," and "[its] description of the CAT matched NAR's description of the CAT on its own website nearly word for word, including references to specific U.S. Patent numbers and the slogan 'Official Tourniquet of the U.S. Army.'" In total, Plaintiffs allege, "NAR has imported no fewer than 57 shipments of medical equipment, including nylon bands and gauze, from Golden Season," and it "continues to import goods originating in China on a regular basis."

Second, Plaintiffs aver evidence that NAR "orchestrated a complex scheme to conceal the true origins of their Products . . . by re-packaging foreign-sourced goods and falsely representing that such goods were U.S. origin." NAR and CATR, Plaintiffs allege, "purchased their Chinese-made goods through suppliers located in Taiwan and Singapore," but instead of "receiv[ing]

[14] For instance, "MedEvac" and "Raptor."

these products directly from East Asian ports," Defendants "caused their Taiwanese and Singaporean suppliers to trans-ship the materials to the United States, where the Products were repackaged and sent to NAR's facilities." Then, Plaintiffs say, "NAR and CATR [] forwarded or repackaged these products again in several facilities they own or operate located in South Carolina," before shipping them to DoD facilities "from South Carolina."

In support of this theory Plaintiffs raise allegations about two boxes of CATs allegedly produced in China. First, they allege their "agents" personally "observed a box filled with CATs . . . in a supply room in Fort Bragg, an Army facility in Fayetteville, North Carolina." One shipping label on the box, Plaintiffs allege, identified no shipper but "stated 'Ship to' the address of NAR's headquarters in Greer, South Carolina"; a second label indicated that the box "had been shipped to Fort Bragg by NAR." A third label "bore the phrase, 'MADE IN U.S.A.'" Second, Plaintiffs allege their "agents" "identified" another box "in a storage room located at Joint Base Lewis-McChord . . . outside of Tacoma, Washington," which "bore a label containing NAR's logo and address as well as a second label bearing CATR's name associated with a Greer, South Carolina address" and "a label deceptively claiming its contents were "'Made in U.S.A.'"

These boxes, Plaintiffs allege, are "typical of the boxes used by NAR and CATR to import goods from China into the United States." In fact, they say, "from 2015 through the present, numerous other similarly-labeled boxes were used by NAR and CATR first, to import CATs from China and then, second, to fraudulently supply these Chinese-made CATs and medical kits containing Chinese-made CATs to DoD." Finally, Plaintiffs allege, "Defendants caused the CATs they sold to DoD to bear no country-of-origin markings," even though "federal law requires these Chinese-made CATs to be marked in a way that clearly identifies them as

being of Chinese origin."

Third, plaintiffs allege that NAR (and, discussed below, CATR) "lack sufficient manufacturing capacity to make all their purportedly Berry[-]Amendment-compliant CATs in the United States" (and they imply that, therefore, the products must have been imported from somewhere else). They explain that "NAR['s] and CATR's Chinese-made products are [] trans-shipped to facilities in South Carolina," where "no additional manufacturing tak[es] place"—in fact, they say, "NAR's facility at 35 Tedwall Court, Greer, South Carolina performs no manufacturing activity" at all. Instead, it "serves as a delivery point for goods manufactured and sent to NAR by third-party suppliers, including its Chinese suppliers." Plaintiffs further allege that "NAR receives these goods at its Greer facility, sorts them and packages them into the various medical kits and sets NAR offers to DoD purchasers." Plaintiffs acknowledge that NAR "operates or did operate a second facility through its Two Rivers Medical division" ("Two Rivers Facility") but they allege that the Two Rivers Facility "employs or did employ imprisoned workers on work release" and "did not perform any manufacturing" either.

From these allegations, Plaintiffs say, can be reasonably drawn the inferences that: "NAR and CATR delivered CATs to the Government containing materials produced in [China]"; that "NAR and CATR also manufactured at least some of these products in China"; and, that "NAR (and, in the case of the CAT, CATR) regularly sells these products to DoD despite their Chinese origin."

2. Discussion

NAR argues that the combination of all these allegations is insufficient to give rise to a "strong inference" that it falsely certified its Chinese-made goods as American-made. It argues that Plaintiffs do not allege facts to show that "any products NAR ultimately sold to the

Government necessarily *had* to have contained Chinese materials," or that "the products NAR sold to the Government *in fact contained* or consisted of materials that were sourced from or through China" (emphasis added).

But NAR seeks to hold Plaintiffs to too high a standard. As explained above, even under the elevated Rule 9(b) standard, Plaintiffs do not need to show that NAR's products "had" to have contained Chinese materials—they just need to allege "particular details of a scheme to" falsely certify the products as American-made, coupled with enough facts to give rise to a "strong inference" that some of the products were in fact not American made. *See Foglia*, 754 F.3d at 156. Here, Plaintiffs have clearly outlined the "details of [the] scheme": First, NAR imported significant quantities of textiles and products from China, including from a company that apparently co-branded certain of those products, and many of NAR's purportedly U.S.-made products "contain fabric or textile components" from China, including "the operative components of the CAT (*i.e.*, the band that is placed around an injured limb and tightened to restrict blood flow) and the Talon Litter." Second, NAR re-packaged them to conceal their origin, and Plaintiffs have evidence of the re-packaged goods. Third, it sold them to DoD (and in fact, could not possibly have produced them in the United States because it lacked the manufacturing capacity).

These facts, if taken as true, sufficiently give rise to these inferences, and therefore to a strong inference that NAR sold products containing Chinese materials to DoD. (Whether these facts are *actually* true is a matter for summary judgment, of course, not a motion to dismiss. *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022).)

Finally, NAR argues that Plaintiffs "do not (and cannot) identify a single CAT that any defendant sold and delivered to the government[that] was manufactured in and imported from

China." This argument also goes too far, as does its argument that Plaintiffs "do not (and apparently cannot) identify a single product that NAR [] sold and delivered to the government that was manufactured in and imported from China, or what, if any, false claims or records were made or tendered to the government in connection with any particular claim for payment." (emphasis added). At this stage the Plaintiffs need not provide any "representative sample[s]"; it is enough that their allegations give rise to an inference of illegality. See *Foglia*, 754 F.3d at 155-57. [15]

Here, Plaintiffs have done more than just "[d]escribe[e] a *mere opportunity* for fraud." *See Foglia*, 754 F.3d at 158. They have supplied enough to give rise to a strong inference. Accordingly, NAR's Motion will be denied as to Count I.

b. CATR's Motion to Dismiss

Plaintiffs' allegations as to CATR are similar to its allegations as to NAR, although the only product with which it alleges CATR was involved is the CAT. Plaintiffs focus primarily on the Fort Bragg and Joint Base Lewis-McChord boxes, Golden Season imports, and CAT's manufacturing capacity.

1. Plaintiffs' CATR-Specific Allegations

First, as to Golden Season and the Fort Bragg and Joint Base Lewis-McChord boxes, Plaintiffs allege the same facts that they alleged as to NAR, with one minor addition: "[T]he Lewis-McChord Box bore a label . . . bearing CATR's name associated with a Greer, South Carolina address."

---

[15] NAR also argues that Plaintiffs "fail to take into account" NAR's own legal action against CAT counterfeiters unrelated to this case. But "a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

Second, as to CATR's manufacturing capacity, Plaintiffs allege additional detail specific to CATR. "CATR and Composite Resources," they allege, "maintain a 55,000 square foot manufacturing facility at 483 Lakeshore Parkway, Rock Hill, South Carolina ('Rock Hill Facility')." They further allege CATR "occupies a portion of one floor of the Rock Hill Facility, about 12,000 square feet of space in total, where it claims that it manufactures the CAT." But, Plaintiffs say, "[u]pon information and belief," the Rock Hill Facility "contains only basic assembly equipment, and it [is] not sufficient to manufacture the volume of tourniquets that CATR and NAR are selling to the Government"—to wit, "approximately 15,000 CAT tourniquets per day," or "10.5 CATs per minute." And, Plaintiffs allege, "upon information and belief," CATR does not "have any other manufacturing facilities in the United States." Therefore, they conclude, "CATR's facilities are not sufficient to produce CATs at the pace . . . CATR claim[s], particularly given CATR's lack of automated manufacturing equipment."

2. Discussion

CATR's arguments in opposition are similar to NAR's. In essence, CATR argues that the connections Plaintiffs ask the Court to draw cross the boundary between properly inferential and impermissibly speculative. For instance, CATR argues that Plaintiffs' allegations regarding the Fort Bragg and Lewis McChord boxes are improperly speculative because they "pre-suppose[]" the answer to the question at stake (*i.e.*, they only support Plaintiffs' claims if it has been independently shown that their contents were in fact made in China). CATR argues along these lines that Plaintiffs' allegation that "some or all of the items delivered to the Government in the Fort Bragg Box contained Chinese-origin materials" is supported only by the conclusory and circular allegation that CATR "manufactured at least some of these products in China." And in fact, CATR contends, "[n]othing on either box remotely suggests—much less reasonably

supports an inference—that it was shipped from China or that its contents were Chinese-made." Likewise, as to Plaintiffs' allegation that CATR "concealed the Chinese origin of the CAT by not marking the CAT with China as the country[]of[]origin": The lack of such a marking, CATR argues, does not by itself reasonably imply that there *should* have been such a marking.

CATR also argues that Plaintiffs' claims regarding its manufacturing capacity are insufficiently particular. The allegation that CATR "only uses 12,000 square feet of the Rock Hill Facility to manufacture the CAT," even alongside an allegation that "there is no 'automated manufacturing equipment' (whatever that means) in that 12,000-square[-]foot space" does not plausibly raise the inference that "the CAT is made not only elsewhere, but in *China*." That, CATR says, "does not pass the pleading standard."

In essence, CATR argues that none of Plaintiffs' allegations—the boxes, the dealings with Golden Season, or the manufacturing capacity—*alone* can justify the inference that it falsely certified certain CATs' country of origin. But at this stage the Court does not assess individual allegations sequentially; the complaint is read (and inferences are drawn) holistically. *See Kedra v. Schroeter*, 876 F.3d 424, 441 (3d Cir. 2017) ([O]n a Rule 12(b)(6) motion, "courts must consider the complaint in its entirety and determine whether the complaint as a whole contains sufficient factual matter to state a facially plausible claim") (citing *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 309-10, (2007)). It is not a matter of "presuppos[ition]," as CATR argues—all of Plaintiffs' allegations are considered together, any inference required is drawn in their favor, and at this stage their allegations need only give rise to a "strong inference" of fraud, not to prove conclusively that fraud occurred. *See St. Luke's Health Network, Inc. v. Lancaster Gen. Hosp.*, 967 F.3d 295, 299 (3d Cir. 2020); *Foglia*, 754 F.3d at 156.

Plaintiffs' allegations as to CATR's manufacturing capacity are particularly strong. They sketch a plausible picture of a facility that lacks equipment complex and extensive enough to produce the volume of CATs CATR claims to produce. CATR argues that Plaintiffs' allegation that it "only uses 12,000 square feet of the Rock Hill Facility to manufacture the CAT" is "wholly unsupported." But it is no problem for Plaintiffs that they have not cited their sources in their complaint—as explained above, factual allegations are taken as true. Here, Plaintiffs have alleged facts that, if true, could plausibly establish it was *impossible* that the CATs sold to DoD were produced in the United States: If CATR lacked the manufacturing capacity to make CATs domestically, they must have been produced elsewhere. That inference, combined with the rest of the full body of Plaintiffs' allegations, is enough to defeat CATR's argument as to Plaintiffs' establishment of falsity.

As they did with regard to NAR, Plaintiffs have pleaded enough factual material that, when considered holistically, plausibly gives rise to the inference that CATR produced CATs in China. Accordingly, CATR's Motion will be denied as to Count One.[16]

---

[16] CATR also attacks Plaintiffs' pleading "upon information and belief." It raises two objections. First, it argues that pleading on information and belief is only allowed in a case governed by Rule 9(b) if "the pleading sets forth specific facts upon which the belief is reasonably based." (quoting *State Farm Mut. Auto. Ins. Co. v. Ficchi*, 2012 WL 1578247, at *5 (E.D. Pa. May 4, 2012)), and Plaintiffs did not set forth any such facts regarding their allegations pleaded on information and belief about CATR's manufacturing capacity. The citation to *Ficchi* is unavailing. For binding authority *Ficchi* cites to *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 319 (3d Cir. 1997), in which the Third Circuit held merely that "a boilerplate allegation that plaintiffs believe the necessary information 'lies in defendants' exclusive control,' if made, must be accompanied by a statement of facts upon which their allegation is based." Here, Plaintiffs have provided significantly more than a "boilerplate" statement that they cannot procure the necessary information.

Second, CATR argues that "district courts in this Circuit oblige plaintiffs even in the pleading stage of FCA actions to provide a statement of efforts undertaken to obtain information from the opposing party" regarding allegations pleaded on information and belief, and here Plaintiffs "have never undertaken any efforts to obtain information from [CATR] regarding the Rock Hill Facility." For support it cites only *U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*,

ii. Counts Two and Three: False Statements and Implied False Statements That NAR Products Were "Sterile" (Against NAR)[17, 18]

Next, Plaintiffs claim NAR violated the FCA by falsely claiming certain of its products were sterilized. NAR sells several products it claims are sterile (as, Plaintiffs say, "required by the United States Food and Drug Administration"): Emergency Trauma Dressings ("ETC"), ARS Decompression Needles ("ARS Needles"), the "CricKit Airway" (a tracheostomy kit), the Casualty Immobilization System (known as "Spider Straps"), the "Talon Litter" (a collapsible litter for carrying wounded soldiers). These products "are intended to be placed in direct contact with an injured soldier's wounds or to be inserted directly into an injured soldier's body."

a. Overview of Sterilization Claim

Plaintiffs say that "[s]tandard industry practice provides" that the packaging of sterilized medical devices "must bear a label reading 'STERILE' alongside a code specifying the manner in which each item was sterilized." They allege that "NAR follows this standard industry practice with respect to the Compressed Gauze, ETD, ARS Needles, and tracheostomy kits sold to DoD."

Beginning in 2015, Plaintiffs allege, Defendants sold Compressed Gauze, ARS Needles,

---

234 F.R.D. 113, 122 (W.D. Pa. 2006). *Bartlett*, as an initial matter, describes a situation different from Plaintiffs': In *Bartlett*, the plaintiffs had *worked for* the defendants, and could therefore be expected to "ha[ve] knowledge of the inner workings" of at least one of the defendants; here, by contrast, Plaintiffs are outsiders. In any case, *Bartlett* cites to *In re American Travellers Corp. Securities Litigation*, 806 F. Supp. 547, 554 (E.D. Pa. 1992), which in turn cites to *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 285 (3d Cir. 1992), *as amended* (May 27, 1992)—which seems to limit its dictate to provide a statement of efforts undertaken to the securities-fraud context.

[17] NAR does not distinguish between Count Two and Count Three in its Motion; rather, it attacks both together on the same grounds (falsity, as with regard to Count One). Therefore, Counts Two and Three will be analyzed together.

[18] Plaintiffs allege Counts Two and Three against NAR and Schein. As discussed above, Schein's Motion will be granted. Therefore, Counts Two and Three will be analyzed as alleged against NAR only.

and tracheostomy kits that bore the required "STERILE" marking and the sterilization-method code "EO." They allege that "EO" refers to the gaseous sterilizing agent ethylene oxide, which "is only effective as a sterilization agent if it comes in contact with the surfaces intended to be sterilized." But EO can only come into contact with a product's surface, Plaintiffs say, if the product is packaged in gas-permeable packaging. "Devices that are packaged in vacuum-sealed or otherwise non-permeable containers cannot be sterilized using ethylene oxide," Plaintiffs maintain—but they say they "and their agents" have "personally observed" Compressed Gauze, ETDs, ARS Needles, and tracheostomy kits "in storage within DoD facilities packaged in vacuum-sealed or otherwise non-permeable containers." Therefore, Plaintiffs say, it "is not possible" that the "EO" products were actually sterilized with EO—a vacuum-sealed container, they allege, "by its nature prevents all gases, including ethylene oxide, from entering the container" and sterilizing the product. The "STERILE" and "EO" labels, Plaintiffs claim, "constitute false representations by NAR to DoD that these products were in fact sterilized with ethylene oxide."

Plaintiffs further allege a similar problem specific to the ARS Needles: "To the extent ARS Needles were sold to the Government with the representation that the product was sterilized using radiation with an extended shelf life (reflected with an 'R' on the packaging), this too was a false representation." Plaintiffs say, "[u]pon information and belief," that the type of polymer used in the catheter on the ARS Needle would not endure the level of radiation treatment required to sterilize the ARS Needles for an extended period without substantial degradation to the product."

In short, Plaintiffs allege that "NAR knowingly and intentionally caused the packaging of the Compressed Gauze, ETDs, ARS Needles, and tracheostomy kits it sold to DoD to bear labels

reading 'STERILE' alongside the code 'EO,'" even though it knew "EO" and "STERILE" represents sterilization by exposure to ethylene oxide, and even though it knew the products were in fact not sterilized by EO because they were packaged in vacuum-sealed containers. They allege that these misrepresentations were material to the Government's decision to purchase the products because "[i]t is readily apparent to all personnel trained to use these products that these devices must be kept sterile to avoid serious infections," and "the Government would not accept," and "would not pay NAR's claims for providing," these products "if NAR did not represent that they were sterile."

b. NAR's Motion to Dismiss

As with Plaintiffs' claims in Count One, NAR only attacks Plaintiffs' establishment of the falsity element. Regarding the allegedly EO-sterilized products, NAR argues that Plaintiffs "possess a theory but nothing more." Plaintiffs, NAR contends, "speculate that it is not possible to sterilize NAR's products using EO gas," and they "allege no factual basis for understanding" NAR's sterilization process. Plaintiffs, NAR argues, "merely speculate that NAR's products are not sterile." NAR also faults Plaintiffs for alleging facts based on "'observ[ations]' at unidentified DoD facilities" by "agents." With regard to the ARS Needles, NAR contends that Plaintiffs have not alleged any false statement at all regarding the Needles' alleged radiation-sterilization: By alleging facts regarding the Needles' radiation sterilization "[t]o the extent" such Needles "were sold to the Government . . . with an 'R' on the packaging," NAR contends, Plaintiffs "are effectively saying '*if* ARS Needles were sold to the [G]overnment" (emphasis added).

As to the allegedly EO-sterilized products, though, NAR understates the facts averred by Plaintiffs. Plaintiffs do not simply *declare* that NAR's products are not sterile. In fact, they

allege much more: Plaintiffs allege that EO sterilization is a process by which the "high pressure in [a] gas chamber forces the ethylene oxide gas into the devices' packaging and sterilizes the surfaces it contacts"; that EO sterilization only works when "the devices to be sterilized are packaged in gas-permeable packaging," so that "the ethylene oxide gas can come into direct contact with the devices' surface"; and that "[d]evices that are packaged in vacuum-sealed or otherwise non-permeable containers cannot be" EO-sterilized. They further allege that "NAR has sold substantial volumes of Compressed Gauze, ETDs, ARS Needles, and tracheostomy kits marked 'STERILE' alongside the code 'EO'" but that "NAR's Compressed Gauze, ETD, and tracheostomy kits are packaged in vacuum-sealed containers," and that "[t]he ARS Needles are packaged in sealed, non-permeable plastic containers" that "[b]y design" prevent "all gases, including ethylene oxide, from coming into contact with their contents." In short, Plaintiffs have averred enough to establish, when their facts are taken as true, that certain NAR products labeled as EO-sterilized were in fact not sterilized, with only minimal inferential gap-filling required.

NAR contends Plaintiffs "do not claim that they have ever tested NAR's products and found that they were not sterile, or reviewed third-party reports or results showing same," but NAR holds Plaintiffs to too high a standard for a motion to dismiss. At trial, of course, any of Plaintiffs' allegations regarding EO-sterilization may prove false, but at this stage the Court may not determine whether Plaintiffs' allegations are scientifically credible. *See Schuchardt v. President of the United States*, 839 F.3d 336, 348 (3d Cir. 2016) (noting that a complaint "may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder") (quoting *Twombly*, 550 U.S. at 573); s*ee also Animal Sci. Prod., Inc. v. China Minmetals Corp.*, 654 F.3d 462, 470 n.9 (3d Cir. 2011), *as amended* (Oct. 7, 2011) (explaining that a district court

"is not permitted to make independent findings of fact" or "assess independently the credibility of allegations" when deciding a Rule 12(b)(6) motion).

As to the alleged radiation-sterilization status of the ARS Needles, though, NAR is right, because Plaintiffs have only pleaded "to the extent" such needles existed. In their Response Plaintiffs say their pleading "to the extent" (ARS Needles bearing an "R" marking were actually sold to the Government) is no issue; they argue they have "alleged . . . other ARS needles contain packaging with an 'R' or 'radiation sterilization' labeling." But NAR has the better of it: Because Plaintiffs have not specified the "extent" to which such "R"-marked needles actually existed, any conclusion regarding the existence of such needles would be impermissibly speculative. *See Twombly*, 550 U.S. at 545 ("Factual allegations must be enough to raise a right to relief above the speculative level.").

Accordingly, the radiation-sterilization allegations will not be considered. Plaintiffs' claims do not depend on them, though—the EO-sterilization claims suffice—and therefore NAR's Motion will be denied as to Counts Two and Three.

IV. CONCLUSION

For these reasons, Schein's Motion will be granted; NAR's and CATR's Motions will be denied.

An appropriate order follows.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.